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| 10/582,660 | 10/12/2006 | David E. Luzzi | UPNA-0083 / P3039 | 6650 |

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| EXAMINER | |
|---|---|
| MILLER, DANIEL H | |
| ART UNIT | PAPER NUMBER |
| 1783 | |

| NOTIFICATION DATE | DELIVERY MODE |
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| 02/03/2011 | ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

eofficemonitor@woodcock.com

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/582,660 | LUZZI, DAVID E. | |
| | Examiner | Art Unit | |
| | DANIEL MILLER | 1783 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *11/19/2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-5,7-17,19-30,32-46 and 48-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-17,19-30,32-46 and 48-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Double Patenting*

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-58 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of copending Application No. 11/720,562. Although the conflicting claims are not identical, they are not patentably distinct from each other because they teach the same major elements including carbon nanotubes coated in silica with the same additional constituents with little to any difference in the structural language of the two claims. No patentable distinction is seen.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### *Claim Rejections - 35 USC § 103*

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-5, -7, 8-10, 23-30, 32-46, 48 and 49-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saitoh WO 2004/039893 abstract translation provided, further citations provided from equivalent disclosure of (US 2006/0052509) in

view of Klein (US PG PUB 2004/0023372) and still further in view of Erianger (US PG PUB 2005/0069947)..

5. Saitoh teaches providing a carbon nanotube composition that contains a conducting polymer (a) or heterocyclic compound trimer (i), a solvent (b) and carbon nanotubes (c), and may additionally contain a high molecular weight compound (d), a basic compound (e), a surfactant (f), a silane coupling agent (g) and colloidal silica h) as necessary; a composite having a coated film composed of the composition; and, their production methods (see abstract of WO document translation).

6. Saitoh teaches a carbon nanotube material coated with or cross-linked with colloidal silica (see abstract and [0098]). The compound comprises heterocyclic trimers that are considered to meet applicant's claimed biofunctional molecule (see [0036-0056]), to the extent to which applicant has defined that term. No patentable distinction is seen.

7. There are no particular limits on the nanotubes of Saitoh from single walled to multi-walled nanotubes (encompassing double walled; see [0074-0075]).

8. Although Saitoh discusses the desire for water solubility of nanotubes in the art (see background), a trait necessary and desirable for interaction with the lipid bilayer, Saitoh is silent as to the method of using the article in a lipid membrane and .a biofunctional component in conjunction with that use.

9. Klein teaches [0021] a tubular nanostructure of the present invention comprises a tubular body having a hydrophobic region flanked by hydrophilic regions. While either or both of the hydrophilic regions may be located at the ends or inward from the ends of

the tubular body, it is preferred that at least one of the hydrophilic regions is located at an end of the tubular body, and more preferably, that both hydrophilic regions are located at the ends of the tubular body. As a structure for forming a pore in a lipid bilayer membrane, and more preferably a cellular membrane, the tubular body of the present invention is preferably sized in its diameter and length with reference to the membrane to be penetrated [0021].

10. The tubular body may comprise carbon nanotubes [0024] and translates molecules across the lipid bilayer (see detailed description specifically [0027]).

11. The addition of biocompatible moieties to the surface (ends) of the nanotube are specifically discussed for interacting with the lipid bilayer (see [0026]).

12. It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the silica coated article of Saitoh in order to preserve the properties of the nanotube and provide the property of solubility (as desired by the primary reference Saitoh; see background) and additionally modify the reference by specifically providing a biocompatable or otherwise bioreactive molecule as taught by Klein to employ the material as a pore for interacting with and embedding in a lipid bilayer as desired by Klein. No patentable distinction is seen.

13. The combined product of Saitoh and Klein are considered porous (as they would be expected to function as a pore to move molecules through the lipid bilayer, as taught by Klein. The nanostructure of Klein is further considered to be a medicament as claimed as it interacts with the lipid bilayer. No patentable distinction is seen.

14. Saitoh teaches colloidal silica but is silent as to the geometry of the particle including spherical. Saitoh does discuss the particles having a range of diameters (see [0100]). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the silica coated article of Saitoh with spherical particles given that the particles with a specific diameter would either be spherical or non-spherical and that one of ordinary skill would consider both and provide the most effective coating for the application through routine experimentation. No patentable distinction is seen.

15. Saitoh (US 2006/0052509) in view of Klein (US PG PUB 2004/0023372) are silent as to the presence of C60 or Horseradish Peroxidase.

16. Erianger discusses the use of nanotubes or Fullerene (C60) as in biological application wherein they can be made soluble [0004 and figures]. Erianger teaches that Horseradish Peroxidase is commonly used to provide markers for the fullerene or nanotube biological material and devices in order to detect them, separate the perform analysis [0136 and 0137-0138].

17. It would have been obvious to one of ordinary skill in the art at the time of the invention to provide C60 fullerenes in the side walls (with one embodiment involving bonding with silane groups as in Saitoh) of the nanotube because it would have been obvious to mix to materials both known (as disclosed by Erianger) to be useful for the same purpose (biological devices) and it would further have been obvious to provide Horseradish Peroxidase is commonly used to provide markers for the fullerene or nanotube biological material and devices in order to detect them, separate the perform analysis [0136 and 0137-0138]. No patentable distinction is seen.

18. Claims 11-17, 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saitoh WO 2004/039893 abstract translation provided, further citations provided from equivalent disclosure of (US 2006/0052509); in view of Klein (US PG PUB 2004/0023372) further in view of Schlaf (US 2005/0241374) and still further in view of Erianger (US PG PUB 2005/0069947).

19. Saitoh teaches providing a carbon nanotube composition that contains a conducting polymer (a) or heterocyclic compound trimer (i), a solvent (b) and carbon nanotubes (c), and may additionally contain a high molecular weight compound (d), a basic compound (e), a surfactant (f), a silane coupling agent (g) and colloidal silica h) as necessary; a composite having a coated film composed of the composition; and, their production methods (see abstract).

20. Saitoh teaches a carbon nanotube material coated with or cross-linked with colloidal silica (see abstract and [0098]). The compound comprises heterocyclic trimers that are considered to meet applicant's claimed biofunctional molecule (see [0036-0056]), to the extent to which applicant has defined that term. No patentable distinction is seen.

21. There are no particular limits on the nanotubes of Saitoh from single walled to multi-walled nanotubes (encompassing double walled; see [0074-0075]).

22. Although Saitoh discusses the desire for water solubility of nanotubes in the art (see background), a trait necessary and desirable for interaction with the lipid bilayer, Saitoh is silent as to the method of using the article in a lipid membrane and .a biofunctional component in conjunction with that use.

23. Klein teaches [0021] a tubular nanostructure of the present invention comprises a tubular body having a hydrophobic region flanked by hydrophilic regions. While either or both of the hydrophilic regions may be located at the ends or inward from the ends of the tubular body, it is preferred that at least one of the hydrophilic regions is located at an end of the tubular body, and more preferably, that both hydrophilic regions are located at the ends of the tubular body. As a structure for forming a pore in a lipid bilayer membrane, and more preferably a cellular membrane, the tubular body of the present invention is preferably sized in its diameter and length with reference to the membrane to be penetrated [0021].

24. The tubular body may comprise carbon nanotubes [0024] and translates molecules across the lipid bilayer (see detailed description specifically [0027]).

25. The addition of biocompatible moieties to the surface (ends) of the nanotube are specifically discussed for interacting with the lipid bilayer (see [0026]).

26. It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the silica coated article of Saitoh in order to preserve the properties of the nanotube and provide the property of solubility (as desired by the primary reference Saitoh; see background) and additionally modify the reference by specifically providing a biocompatable or otherwise bioreactive molecule as taught by Klein to

employ the material as a pore for interacting with and embedding in a lipid bilayer as desired by Klein. No patentable distinction is seen.

27. The combined product of Saitoh and Klein are considered porous (as they would be expected to function as a pore to move molecules through the lipid bilayer, as taught by Klein. The nanostructure of Klein is further considered to be a medicament as claimed as it interacts with the lipid bilayer. No patentable distinction is seen.

28. Saitoh teaches colloidal silica but is silent as to the geometry of the particle including spherical. Saitoh does discuss the particles having a range of diameters (see [0100]). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the silica coated article of Saitoh with spherical particles given that the particles with a specific diameter would either be spherical or non-spherical and that one of ordinary skill would consider both and provide the most effective coating for the application through routine experimentation. No patentable distinction is seen.

29. Neither Saitoh or Klein teach the nanotubes as part of a probe or AFM probe tip.

30. Schlaf teaches it is known in the art to provide a nanotube tipped cantilever probe tip specifically for AFM (see figures and paragraphs 002-005). The CNT probe tip offer not only extraordinary nanometer scale resolution but have high strength and ability to handle deformation [paragraph 0004].

31. It would have been obvious to one of ordinary skill in the art at the time of the invention to provide an atomic force microscope (AFM) tip comprising carbon nanotubes in order to allow for a AFM with extraordinary nanometer scale resolution and high

strength and ability to handle deformation [paragraph 0004]. No patentable distinction is seen.

32. Saitoh (US 2006/0052509) in view of Klein (US PG PUB 2004/0023372) are silent as to the presence of C60 or Horseradish Peroxidase.

33. Erianger discusses the use of nanotubes or Fullerene (C60) as in biological application wherein they can be made soluble [0004 and figures]. Erianger teaches that Horseradish Peroxidase is commonly used to provide markers for the fullerene or nanotube biological material and devices in order to detect them, separate the perform analysis [0136 and 0137-0138].

34. It would have been obvious to one of ordinary skill in the art at the time of the invention to provide C60 fullerenes in the side walls (with one embodiment involving bonding with silane groups as in Saitoh) of the nanotube because it would have been obvious to mix to materials both known (as disclosed by Erianger) to be useful for the same purpose (biological devices) and it would further have been obvious to provide Horseradish Peroxidase is commonly used to provide markers for the fullerene or nanotube biological material and devices in order to detect them, separate the perform analysis [0136 and 0137-0138]. No patentable distinction is seen.

### ***Response to Arguments***

35. Applicant's arguments filed 11/19/2010 have been fully considered but they are not persuasive.

36. The 102 rejections have been withdrawn due to attorney argument and amendments which have rendered the rejections moot.

37. Applicant has argued that the materials of an enzyme and a silica coating are optional features of two different references and therefore there combination is only through improper hindsight using the instant reference as a blueprint. The examiner respectfully disagrees.

38. Erianger discusses the use of nanotubes or Fullerene (C60) as in biological application wherein they can be made soluble [0004 and figures]. Erianger teaches that Horseradish Peroxidase is commonly used to provide markers for the fullerene or nanotube biological material and devices in order to detect them, separate the perform analysis [0136 and 0137-0138].

39. It would have been obvious to one of ordinary skill in the art at the time of the invention to provide C60 fullerenes in the side walls (with one embodiment involving bonding with silane groups as in Saitoh) of the nanotube because it would have been obvious to mix to materials both known (as disclosed by Erianger) to be useful for the same purpose (biological devices) and it would further have been obvious to provide Horseradish Peroxidase is commonly used to provide markers for the fullerene or nanotube biological material and devices in order to detect them, separate the perform analysis [0136 and 0137-0138]. No patentable distinction is seen.

40. There is clear motivation to provide the enzyme markers for practical application and Horseradish Peroxidase is a marker known to be used for that purpose in the art. No patentable distinction is seen.

41. Modified 103 rejections maintained.

***Conclusion***

42. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANIEL MILLER whose telephone number is (571)272-1534. The examiner can normally be reached on M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Sample can be reached on (571)272-1376. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Angela Ortiz/
Supervisory Patent Examiner, Art Unit 1798

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